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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/099,663 | 03/14/2002 | Nelson D. Horseman | AVI021 | 2987 |

7590 11/07/2003

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EXAMINER

WILSON, MICHAEL C

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1632

DATE MAILED: 11/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/099,663 | HORSEMAN ET AL. | |
| | Examiner | Art Unit | |
| | Michael C. Wilson | 1632 | |

-- *Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-49 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, 6-8, 12-16, 18-28, 30-42, drawn to a nucleic acid sequence comprising an avian gut-specific control region comprising SEQ ID NO:1, a vector comprising said sequence and a method of expressing a heterologous protein in a cell using said sequence, classified in class 435, subclass 320.1.
- II. Claims 1-3, 5, 9-15, 17-27, 29-42, drawn to a nucleic acid sequence comprising an avian gut-specific control region comprising SEQ ID NO:2, a vector comprising said sequence and a method of expressing a heterologous protein in a cell using said sequence, classified in class 435, subclass 320.1.
- III. Claims 43-49, drawn to a transgenic avian comprising SEQ ID NO:1, classified in class 800, subclass 19.
- IV. Claims 43-49, drawn to a transgenic avian comprising SEQ ID NO:2, classified in class 800, subclass 19.

The inventions are distinct, each from the other because of the following reasons:

Groups I and II are patentably distinct because the nucleic acid sequence of Group I comprises coding and non-coding iFABP regions while the nucleic acid sequence of Group II is the iFABP promoter. The burden required to search both SEQ

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ID NO:1 and 2 together would be undue. The search required for Group I includes sequences not required in the search in Group II.

Groups I and III are patentably distinct because the nucleic acid sequence can be used to make a probe while the transgenic avian may be used as an ornamental bird. The protocols and reagents required for DNA and for avians are materially distinct and separate. The nucleic acid sequence of Group I does not require the transgenic of Group III and the transgenic of Group III does not require the nucleic acid sequence of Group I.

Groups I and IV are patentably distinct because the nucleic acid sequence can be used to make a probe while the transgenic avian may be used as an ornamental bird. The protocols and reagents required for DNA and for avians are materially distinct and separate. The nucleic acid sequence of Group I does not require the transgenic of Group IV and the transgenic of Group IV does not require the nucleic acid sequence of Group I.

Groups II and III are patentably distinct because the nucleic acid sequence can be used as a probe while the transgenic avian may be used as an ornamental bird. The protocols and reagents required for DNA and for avians are materially distinct and separate. The nucleic acid sequence of Group II does not require the transgenic of Group III and the transgenic of Group III does not require the nucleic acid sequence of Group II.

Groups II and IV are patentably distinct because the nucleic acid sequence can be used to make a probe while the transgenic avian may be used as an ornamental

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bird. The protocols and reagents required for DNA and for avians are materially distinct and separate. The nucleic acid sequence of Group II does not require the transgenic of Group IV and the transgenic of Group IV does not require the nucleic acid sequence of Group II.

Groups III and IV are patentably distinct because the transgenic of Group I can be used to overexpress iFABP while the transgenic of Group II can be used to express a heterologous protein in the gut. The protocols and reagents required for a transgenic overexpressing iFABP and for a transgenic expressing a heterologous protein in the gut. The transgenic of Group III does not require the transgenic of Group IV, and the transgenic of Group IV does not require the transgenic of Group III.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I-IV are different, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 872-9306.

Michael C. Wilson



MICHAEL WILSON
PRIMARY EXAMINER